PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE lection of information unless it displays a valid OMB control number. aperwork Reduction Act of 1995, no persons are required to respond to Application Number 10/642.255 RANSMITTAL Filing Date August 15, 2003 **EFORM** First Named Inventor Dole et al. Art Unit respondence after initial filing) **Examiner Name** Attorney Docket Number y w/refs 52339AUSM1 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board Licensing-related Papers of Appeals and Interferences Fee Attached Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Terminal Disclaimer **Extension of Time Request** Identify below): 1449 Form with references Request for Refund **Express Abandonment Request** Return Post Card CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Wendy L. Washtien, Ph.D. Individual name Signature Nagutier Date CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Typed or printed name Mary Ann Flore

This collection of information is required by 37 Cff 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature

Date



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Dole et al.

Serial No. 10/642,255 : Group Art Unit: Not Yet Known

Filed August 15, 2003 : Examiner: Not yet known

For: GENE THERAPY FOR CRITICAL LIMB ISCHEMIA WITH WILD-TYPE OR

MUTANT eNOS

Mail Stop Patent Application Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

## **INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. §1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449. As to any reference supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. §1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Pursuant to 37 CFR 1.98(d), copies of these documents are not provided herewith, but may be made available to the Examiner if required.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully Submitted,

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FCRM PTO-1449 (REV-180)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE					APPLICATION NO. 10/642,255				
INFO	ORM	ATION DISCLOSUR	E STATEMEN	APPLICANTS Dole et al.							
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U.S. PATENT DOCUMENTS											
*EXAMINER INITIAL		DOCUMENT NUM	BER	DATE	NAME	CLAS	ss	SUBCLASS	FILING DATE IF APPROPRIATE		
FOREIGN PATENT DOCUMENTS											
		DOCUMENT NUMBER	DATE		COUNTRY			TRANSLATION YES NO			
	1.	WO 00/28076	18MAY00	PCT							
	2.	WO 00/62605	26OCT00	PCT							
	3.		Fleming, I. et al., "Phosphorylation of Thr <sup>495</sup> Regulates Ca <sup>2+</sup> /Calmodulin-Dependent Endothelial Nitric Oxide Synthase Activity," <i>Circ Res</i> , 88:e68 -e75; 2001.								
	4.	· ·	Govers, R. et al., "Cellular Regulation of Endothelial Nitric Oxide Synthase," <i>Am J Physiol Renal Physiol</i> 280:F193-F206; 2001.								
	5.	· ·	Marletta, M. A., "Another Activation Switch for Endothelial Nitric Oxide Synthase: Why does it have to be so complicated," <i>TRENDS in Biochemical Sciences</i> Vol.26:No.9; 2001.								
	6.	Phosphorylation	Mitchell, B. J. et al., "Coordinated Control of Endothelial Nitric-Oxide Synthase Phosphorylation by Protein Kinase C and the cAMP-dependent Protein Kinase," <i>J. Biol. Chem.</i> , 276: 17625 – 17628; 2001.								
	7.	Angiogenesis	Smith, R. S. et al., "Human Endothelial Nitric Oxide Synthase Gene Delivery Promotes Angiogenesis in a Rat Model of Hindlimb Ischemia," <i>Arterioscler. Thromb. Vasc. Biol.</i> , 22: 1279 – 1285; 2002.								
	8.		Rissanen, T. T. et al., "Gene therapy for therapeutic angiogenesis in critically ischaemic lower limb – on the way to the clinic," <i>Eur J Clin Invest</i> 31(8):651-666; 2001.								
EXAMINE	R	•			DATE CONSIDERED						
* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).											

Forms/Pat/P7-27 [01/31/01]